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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,914	05/02/2001	Y. Tom Tang	PF-0621 USN	5287

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EXAMINER	
FRONDA, CHRISTIAN L	

ART UNIT	PAPER NUMBER
1652	23

DATE MAILED: 10/02/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/830,914	TANG ET AL.	
	Examiner	Art Unit	
	Christian L Fronda	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 21-40 is/are pending in the application.

4a) Of the above claim(s) 21,22 and 32-40 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 23-31 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 02 May 2001 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Newly submitted claims 21, 22, and 32-40 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons stated below.

As sated in the Office Action dated 4/4/2003 (Paper No. 19) the originally filed inventions listed as Groups I-VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The special technical feature of the inventions listed as Groups I-VII is a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 1 and fragments thereof. However, Kinkema et al. (Accession Q39157) teach a myosin heavy chain polypeptide comprising a fragment of SEQ ID NO: 1 (see alignment attached to the previous Office Action dated 4/4/2003).

Since Applicants have not contributed a special technical feature over the prior art, Groups I-VIII do not have a single general inventive concept and therefore lack unity of invention.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 21, 22, and 32-40 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

2. Claims 23-31 are under consideration.

Claim Objections

3. Claims 23-31 are objected to because they depend from nonelected claim 21 or 22. Applicants are required to cancel the claims, or amend the claims to place the claims in proper dependent form, or rewrite the claims in independent form.

Claim Rejections - 35 U.S.C. § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and

requirements of this title.

5. Claims 23-31 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

Applicants' arguments filed 7/24/03 have been fully considered but they are not persuasive. Applicant's position is that the claimed invention has utility since it is asserted that the invention has practical in gene and protein expression monitoring applications and that the claimed polynucleotide encodes for a protein in the myosin family. The Examiner disagrees for reasons of record and for the following reasons stated below.

Applicants disclose the nucleotide sequences of SEQ ID NO: 2, the deduced amino acid sequence of the protein encoded as SEQ ID NO: 1, and assigned the protein of SEQ ID NO: 1 as a "new human myosin heavy chain homolog (MHCH)". However, the specification does not disclose the **specific** function of the protein of SEQ ID NO: 2 or its specific relationship to any disease. Homology is not a disclosure of how to use the protein or polynucleotide encoding the protein of SEQ ID NO: 2. While the claimed invention can be used in gene and protein expression monitoring experimentations, the specification does not teach any meaningful interpretation of data collected from such experimentations. Nor does the specification teach how to use any identified compound which modulates the expression of the claimed invention.

Substantial utility is one that provides a specific benefit in currently available form at the time of filing of the invention. However, the main utility of the nucleic acid and protein is to carry out further research to identify the biological function and possible diseases associated with the protein. Utilities that require or constitute carrying out further research to identify or reasonably confirm a specific use are not substantial utility and do not provide a specific benefit. Thus, the claimed invention has no specific or substantial asserted utility.

Claim Rejections - 35 U.S.C. § 112, 1st Paragraph

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 23-31 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above in the rejection of claims 23-31 under 35 U.S.C. 101, one skilled in the art clearly would not know how to use the claimed invention.

Furthermore, claims 23, 26, 27, 28, 30 which encompass any polynucleotide of any nucleotide sequence encoding a polypeptide having an amino acid sequence at least 90% identical to SEQ ID NO: 1, any polynucleotide of any nucleotide sequence having 70% identity to any polynucleotide encoding SEQ ID NO: 1 or any fragment thereof which has ATPase activity, and any polynucleotide having 70% identity to SEQ ID NO: 2 are not enabled by the specification.

Applicants' arguments filed 7/24/03 have been fully considered but they are not persuasive. Applicant's position is that the claimed invention is enabled by the specification since the claims are drawn to naturally-occurring variants which can be screened for using hybridization and PCR. The Examiner disagrees for reasons of record and for the following reasons stated below.

The specification provides guidance for screening and searching for the claimed invention which **is not guidance for making the claimed invention.** In order to make the claimed invention one of ordinary skill in the art must perform an enormous and undue amount of experimentation since the specification does not teach the specific structural/catalytic amino acids and the structural motifs essential for protein activity/function which cannot be altered. Such experimentation entails selecting specific nucleotides to change (deletion, insertion, substitution, or combinations thereof) in a polynucleotide to make the claimed polynucleotide and determining by assays whether the polypeptide has activity. Furthermore, such experimentation is well outside the realm of routine experimentation and predictability in the art of success in determining whether the resulting polypeptide has activity is extremely low since no information is provided by the specification regarding the specific catalytic amino acids and the structural motifs essential for enzyme structure and activity/function which must be preserved.

The Examiner finds that one skilled in the art would require additional guidance, such as information regarding the specific catalytic amino acids and the structural motifs essential for activity/function which must be preserved. Without such a guidance, the experimentation left to those skilled in the art is undue.

8. Claims 23, 26, 27, 28, 30, and 31 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims are directed to any polynucleotide of any nucleotide sequence encoding any polypeptide comprising an amino acid sequence of having at least 90% identity to SEQ ID NO: 1, any polynucleotide of any nucleotide sequence encoding any immunogenic fragment comprising at least 15 contiguous amino acid residues of SEQ ID NO: 1, any polynucleotide of which is at least 70% identical to SEQ ID NO: 2, and any polynucleotide of 25 contiguous

nucleotides of SEQ ID NO:2 or complement thereof.

The specification, however, only provides the following representative species encompassed by these claims: a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 2 and a polynucleotide encoding a polypeptide consisting of the amino acid sequence SEQ ID NO: 1. There is no recitation of any particular structure to function/activity relationship in the claims. There is no written description for any polynucleotide of any nucleotide sequence encoding any polypeptide comprising an amino acid sequence of having at least 90% identity to SEQ ID NO: 1, any polynucleotide of any nucleotide sequence encoding any immunogenic fragment comprising at least 15 contiguous amino acid residues of SEQ ID NO: 1, any polynucleotide of which is at least 70% identical to SEQ ID NO: 2, and any polynucleotide of 25 contiguous nucleotides of SEQ ID NO:2 or complement thereof.

Applicants have failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L. Fronda whose telephone number is (703)305-1252. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703)308-3804. The fax phone number for this Group is (703)308-0294. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703)308-0196.

CLF

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